RI Consultants LLC

K090321

Section 5
510(k) Summary

MAY 27 2009

Section 807.92(a)

(1) Submitter

RI Consultants LLC
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Establishment Registration No.: Not yet applied for in accordance with 21CFR 807.21

Contact Person: Thomas Golembeski
Director
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(2) Device Name:

Classification Name: Radionuclide Brachytherapy Source (892.5730) (90 KXK)

Common or Usual Name: Brachytherapy Source

Proprietary Name: RIC Conformal Source Model 100

(3) Legally Marketed Predicate Devices:

BEBIG Plaques RUM101-RUM114
K931393 dated 16 March 1994, and

New England Nuclear ^{90}Strontium NB-1 Eye Applicator
Pre-Amendment Device

(4) Description of RIC Conformal Source Model 100:

RIC Conformal Source Model 100 Brachytherapy Source is designed for use in medical Brachytherapy applications. The capacity of each source is up to 200 millicuries of ^{32}Phosphorus. The physician could prescribe a physical size up to 50mm by 100mm.

This RIC Conformal Source is a flat flexible planar radioactive ^{32}Phosphorus polymeric film that could be made conformal to different surface geometries such as flat, concave or convex semi-cylindrical shapes through the use of an appropriately shaped shield / holder or by placement on an area to be treated and made conformal by the weight of a flexible compliant media. At the option of the prescribing physician, the RIC Conformal Source could be attached to a manual radionuclide applicator (available from RI

Consultants, Class I device, 892.5650) to facilitate handling and to provide shielding to the clinician.

The RIC Conformal Source consists of ^{32}Phosphorus chemically bound to the biocompatible polymeric film. The polymeric film thickness is 0.3mm (0.012 inch) to 0.7 mm (0.028 inch). The ^{32}Phosphorus polymeric film is then coated with a flexible biocompatible silicone coating which is about 0.01 mm (0.0005 inch) thick.

The ^{32}Phosphorus is chemically bonded to the polymer molecule and is an integral part of the film.

(5) Intended Use

The intended use of RIC Conformal Source Model 100 Brachytherapy Source is for the treatment of cancer by temporary intraoperative or surface irradiation.

(6) Technological Characteristics:

RIC Conformal Source Model 100 Brachytherapy Source is similar to the predicate brachytherapy source, BEBIG Plaques RUM101-RUM114, K931393 dated 16 March 1994, and New England Nuclear ^{90}Strontium NB-1 Eye Applicator, Pre-Amendment Device, that utilizes β^- particles from ^{90}Yttrium.

The RIC Conformal Source Model 100 Brachytherapy Source is provided non-sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Mr. Thomas Golembeski
Director
RI Consultants LLC
1 Chagnon Lane
HUDSON NH 03051

Re: K090321
Trade/Device Name: RIC Conformal Source Model 100 Brachytherapy Source
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: ONL, KXK
Dated: April 14, 2009
Received: April 22, 2009

Dear Mr. Golembeski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

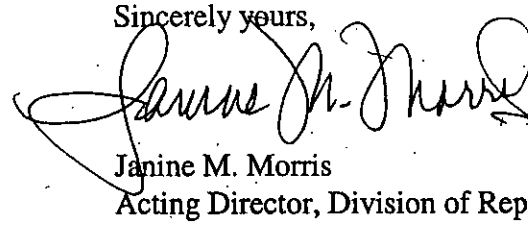
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K090321

Device Name: RIC Conformal Source Model 100 Brachytherapy Source

Indications for Use:

RIC Conformal Source Model 100 Brachytherapy Source, containing ^{32}Phosphorus with activity up to 200 mCi is indicated for treatment of temporary intraoperative, interstitial, intracavitary or surface application to treat selected localized tumors. It can be used either as primary treatment or as treatment for residual disease after excision of primary or recurrent tumors. This brachytherapy source may be used concurrently with or following treatment with other interventions, such as external beam therapy. Chordomas, chondrosarcomas, soft tissue sarcomas, skin cancers and other accessible tumors could be commonly treated by the RIC Conformal Source Model 100 Brachytherapy Source, containing ^{32}Phosphorus.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090321